IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Cassone, Alphonse	Docket No:	4139P2202
Serial No:	09/619,357	Examiner:	DeMille, Danton
Filed:	07/19/00	Art Unit:	3764

Title: METHOD FOR TREATING BODY TISSUE DISEASE WITH ACOUSTIC WAVES

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REPLY BRIEF

As a preliminary point, the Examiner's Answer appears to ignore the reasons given in Appellant's Appeal Brief that demonstrate the Examiner's error in rejecting Appellant's claimed invention under 35 U.S.C. 103(a) that is based on Balamuth in view of Nedwell. In particular: (1) neither reference alone nor in combination suggests treating a person outside of and away from, and not in, the container as claimed by the Appellant; (2) each reference teaches away from Appellant's claimed invention by suggesting an alleged benefit only by immersing a person in a fluid, therefore, the combination also teaches away from Appellant's claimed invention; (3) neither reference alone nor in combination inherently practices Appellant's claimed invention; and (4) the references cannot be properly combined as the Examiner suggests, as there is no teaching, suggestion, or motivation for the combination, however, there is strong motivation to not combine the references. Appellant respectfully submits that for these above-noted reasons, unchallenged and non-responded to in the Examiner's Answer, the Examiner's obviousness rejection is improper and reversal of the Examiner's decision is respectfully solicited.

The remainder of this Reply Brief will address the arguments introduced by the Examiner in the Examiner's Answer in the order that they were presented.

I. The Cited References Do Not Comprehend Or Disclose Treating a Person in Contact With the Outside or Exterior Portion of a Container Containing a Submerged Transducer Located Therein

The Examiner asserts that the therapeutically beneficial distance of the claimed invention may be zero distance (which means contact with the container), and that the combination of Balamuth with Nedwell comprehends treating a person in contact with the outer surface of the container. Examiner's Answer, p. 5. However, each of the reasons introduced in Appellant's Appeal Brief and enumerated above continue to demonstrate the rejection is improper, even at zero distance. Balamuth and Nedwell fail to suggest treating a person outside of a container, even if in contact with the outside wall. The references instead teach away from such treatment by claiming benefit only for a person immersed in the fluid (inside the container) in response to specific physical characteristics of the fluid medium. For example, the low-frequency pulmonary resonance of Nedwell to loosen mucus and the ultrasonic micromessaging of Balamuth for relaxation would not be available to a person that is not in the fluid, but instead in contact with the outside walls of the respective container (not shown) as alleged by the Examiner. Simply stated, the Examiner is taking the person in the fluid in the container of each cited reference and, in effect, placing each person outside the container. Finally, as demonstrated in Appellant's Appeal Brief and outlined above, there is no teaching or suggestion to combine Balamuth and Nedwell, and strong motivation to not make the Examiner's proposed combination as it would render each device inoperable for its intended use. There is simply no support in the cited references, or their combination, for the Examiner's suggestion that it would be obvious to treat a person having an inflammatory musculoskeletal connective tissue disorder by pressing the person against the outside of the container of Balamuth or Nedwell instead of within the fluid as taught by each reference.

Appellant further respectfully points out that the Appellant's application as originally filed clearly distinguished the claimed methods of treatment by immersing a portion of a person in the container (prior Claim 21) and treatment by positioning a person a distance away from the container (Claims 1-20). As noted in Appellant's Appeal Brief and confirmed in the Examiners Answer, prior Claim 21 has been

cancelled, and Appellant is only pursuing patent protection for the remaining Claims directed to treatment of a person positioned a distance from the container.

II. The Cited References Do Not Render Obvious Appellant's Method of Treating a Person a Distance From a Fluid-Filled Container Containing a Submerged Transducer Located Therein

Even though "the prior art may not teach spacing the patient with a space of air between the container and the patient," Examiner's Answer p. 4, the Examiner apparently asserts that removing a patient outside of the fluid-filled container of Balamuth or Nedwell (or their combination) to treat a person does not involve an inventive step. Examiner's Answer, p.5. In support of this assertion, the Examiner relies upon Alton and Eakin which are references while previously generally cited by the Examiner, but never applied against Appellant's claims and, therefore, are not the grounds for the obviousness rejection at issue as noted in the Examiner's Final Office Action.

Again, both Nedwell and Balamuth teach away from positioning a person outside of their respective containers, as the treatment disclosed in each relies on the interaction of the fluid medium with the person's body, either in a chest-vibrating capacity (Nedwell) or an ultrasonic micro-messaging relaxing capacity (Balamuth).

Balamuth teaches therapeutic benefits requiring receiving vibrations from a fluid, not aerial, medium: "a patient submerged in a bathtub of warm water, being irradiated by modulated ultrasonic waves... will have psychosonic benefits," and "it must be appreciated that music received this way... is a completely different phenomenon than the usual method of... aerial acoustic vibration." Balamuth, Col. 1, Ln. 33-44. Balamuth also teaches that this benefit only occurs to a patient within the container: "[i]t is of the greatest importance to appreciate [the results are due to the synergistic effects of the audio, visual, and micro-messaging systems of the bath] and in so being the total effect produced cannot be ascribed to each element separately. But rather, the system must be combined as a whole, and the effects produced are uniquely the result of the whole environment." Balamuth, Col. 2, Ln. 22-27 (emphasis added). Therefore, Balamuth strongly teaches away from Appellant's claimed invention, which employs both aerial transmission of acoustic energy and therapeutic effects to a person positioned outside the environment, or container.

Nedwell also specifically teaches away from using air as a medium for propagating therapeutic vibrations: "[s]ound in water interacts with the body more strongly than sound in air due to the similar physical properties of water and body tissue." Nedwell, Col. 1, Ln. 43-45. Additionally, Nedwell teaches therapeutic benefits from vibrations that exist only when a person is immersed in fluid and not in air. '[I]t has been found that there additionally exists a Helmholtz resonance of the lungs at a frequency of about 16 Hz in a submerged adult." Nedwell, Col. 2, Ln. 8-10 (emphasis added). Therefore, Nedwell teaches away from Appellant's claimed invention using the aerial transmission of acoustic energy and also teaches away from Appellant's claimed treatment of a person not immersed in the fluid housing the transducer.

Furthermore, the additional references of Eakin and Alton (which are not cited in the Examiner's Final Office Action as grounds for his obviousness rejection) fail to demonstrate that positioning a person outside a fluid-filled container housing a submerged transducer to receive treatment is somehow obvious. Eakin describes positioning a person above loudspeakers to receive a messaging treatment from the sound vibrations. Eakin makes no mention of immersing the loudspeaker in a fluid-filled chamber, and instead teaches against the use of fluid to propagate acoustical energy: "such systems are too tightly coupled to be conducive to relaxation." Eakin, Col. 1, Ln. 46-47. Similarly, Alton describes positioning a person a distance from loudspeakers to receive a messaging treatment. Alton also makes no mention of immersing the loudspeakers in a fluid-filled container.

In summary, Balamuth and Nedwell each teach away from treating a person that is not immersed in the fluid containing the transducer. Because the references cited for the obviousness rejection each teaches away from Appellant's claimed invention, their combination must also teach away from such claimed treatment. These references are defective in supporting the Examiner's assertion that removing a patient outside of the fluid-filled container of Balamuth or Nedwell (or their combination) to treat a person does not involve an inventive step, but instead tend to support (Appellant's position) on the non-obviousness of Appellant's claimed invention. This defect in the Examiner's rejection position based on obviousness is not corrected by the introduction of Eakin or Alton, which (apparently) are introduced to show that acoustic vibrations generated by a

loudspeaker in air can propagate for a distance in air. Neither Eakin nor Alton use a transducer submerged in a fluid-filled container to treat a person positioned a distance outside of and away from the container, and do not, in any way, support the Examiner's 103(a) rejection.

III. The Benefits Alleged by Alton Do Not Render Appellant's Claimed Invention As Being Obvious

The Examiner appears to raise a new ground of rejection in the Examiner's Answer, that because Alton alleges to help treat "every disease from cancer to the common cold" by using vibrations to message a person and reduce stress, thereby increasing the person's ability to combat diseases, Appellant's claimed method is rendered obvious. Examiner's Answer, p. 6. The Examiner apparently asserts that any treatment for any disease, and particularly as defined in Appellant's claimed invention, that involves exposing a person to any sort of vibration could be attributed to stress reduction, and therefore comprehended by Alton.

Appellant first respectfully notes that the sole issue before the Board is the rejection of the claimed invention as obvious over Balamuth in light of Nedwell. Although cited as pertinent, Alton has to Appellant's knowledge never been relied on as a ground of rejection prior to the Examiner's Answer. Additionally, the Examiner's theory that the method of treatment of the claimed invention is comprehended by Alton's stress-reducing message apparatus has also, to Appellant's knowledge, never been asserted or suggested prior to the Examiner's Answer.

Appellant respectfully notes that testing of the method claimed by Appellant has been underway under the auspices of the University of Nevada Las Vegas. Specifically, the claimed method has been tested on patients suffering from peripheral vascular disease ("PVD"), a type of circulatory disorder, and also on patients suffering from osteoarthritis. Each study has resulted in an article that has been submitted for publication in a peer-reviewed medical journal. Copies of these articles are attached hereto. Appellant believes these articles are already of record in the prosecution and were submitted on or around June

10, 2002 in response to a non-final rejection by the prior Examiner of this subject patent application. However, because the present Examiner appears to raise a new ground of rejection in the Examiner's Answer, based on the Examiner's own apparently personal interpretation of physiological mechanisms at work, Appellant is resubmitting the articles herewith.

Appellant notes the well-established rule "that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests." Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565 (Fed. Cir. 1983). Nevertheless, the osteoarthritis study submitted herewith states that: "Audible sound has been shown to have physiological effects on the body and its metabolic processes by activating subcortical neural systems. By activating these systems, the cardiovascular, metabolic, endocrine, reproductive, and neurological functions of the body may be altered." "Effects of a Low Frequency Sonic Waveform on Osteoarthritis: A Pilot Study," p. 3, attached hereto. This represents a possible explanation for the beneficial effects shown from treatment of patients with Appellant's claimed invention, independent of and not comprehended by the message-induced stress reduction taught by Alton. Additionally, the PVD study reports that "it is believed that peripheral vascular disorders involve changes in vessel structure and function," and warns that the actual physiological reactions to the frequency of the study "are mostly unknown." "The Effects of a Low Frequency Acoustic Waveform on Peripheral Vascular Disease: A Pilot Study" p. 174, attached hereto.

Furthermore, Alton teaches therapeutic benefit by the massaging action induced by acoustic energy "at or below 40 Hz," listing benefits for this particular frequency range as efficient coupling to skin, muscle, bone and organs, and the inaudible nature of these frequencies for relaxation purposes. Thus, the therapy taught by Alton occurs well outside Appellant's claimed range of treatment of between 400-800 Hz. In addition, the PVD study noted in one of the articles submitted herewith warns against applying the results of infrasound studies occurring at 16 Hz, a frequency comprehended by Alton, to those of the

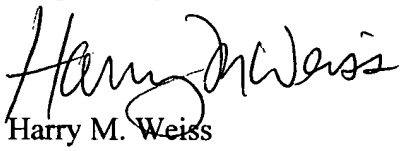
Appellant's: "the results of those studies cannot be extrapolated to the present study because frequency and pressure ratios (decibels) are very different." Id.

Appellant respectfully submits that Appellant's Claimed Invention is deserving of patent protection because it describes a useful and functional method which patentably distinguishes over the cited prior art. Appellant respectfully submits that for the reasons stated above, in addition to those brought up in Appellant's Appeal Brief and unchallenged in the Examiner's Answer, the obviousness rejection is improper and reversal of the Examiner's Final Rejection is respectfully solicited.

REQUEST FOR ORAL HEARING

Appellant respectfully requests an oral hearing before the Board of Patent Appeals. Please deduct any charges that may be incurred by this Reply Brief or Request for Oral Hearing from our Deposit Account No. 23-0830.

Respectfully Submitted,



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The Effects of a Low Frequency Ac ustic Waveform on Osteoarthritis: A Pilot Study

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Objective: To investigate the effects of a low frequency acoustic waveform on pain and range of motion (ROM) for patients with osteoarthritis (OA).

Methods: Twenty one adults with OA (7 males, 14 females) were recruited from local advertisements to participate in a quasi-experimental pre-test, post-test, 24 hour post-test design using a new technology called the Cassone transducer. Participants were treated in a seated position while facing the transducer in a circular fashion approximately one foot away from the column for 25 minutes. ROM was measured for the wrist, knee, and hip using goniometry, and pain was assessed using a visual analog pain scale across all conditions.

Results: Patients had less pain immediately ($p < 0.001$) and at 24 hours ($p < 0.01$). Range of motion significantly improved in right and left hip flexion ($p < 0.01$), left wrist flexion ($p < 0.01$), and left knee flexion ($p < 0.05$) pre to post. Significant improvements were noted in hip flexion (left, $p < 0.001$; right, $p < 0.01$) and wrist flexion (left, $p < 0.05$; right, $p < 0.01$) after 24 hours, but not in knee flexion or wrist extension ROM.

Conclusion: The results of this pilot study suggest that use of acoustic energy as an alternative form of therapy may improve ROM and decrease pain.

Acknowledgements
We wish to thank Medsonix for providing the use of their facility for this study. The authors also express their gratitude to Alphonse Cassone for his technical assistance and the use of his patent technology.

The effects of a low frequency acoustic waveform on peripheral vascular disease: a pilot study

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SUMMARY. Objective: To evaluate the effects of a low frequency acoustic waveform on peripheral vascular disease (PVD). Design: Pilot study utilizing a one-group pre-intervention, post-intervention design. Setting: Adults with peripheral vascular disease were recruited through local advertisements. The study was conducted at a local facility housing the electroacoustic transducer. Intervention: A 25-min exposure to an electroacoustic transducer. Outcome measures: Pre- and post-measurement of Doppler ultrasound blood-flow velocities in 10 arteries, ankle brachial index (RBI), foot assessment, and 1-week post telephone survey. Results: A significant increase was noted in the right ankle brachial index (RABI) but not the left. Blood flow increased in all arteries, significantly in four. Thirteen participants reported improvement in symptom of peripheral vascular disease over the following week. Conclusions: While conclusions must be viewed cautiously, the significant differences noted warrant further study to examine effects of acoustic waveforms on peripheral vascular disease.

INTRODUCTION

Peripheral vascular disease (PVD) is a disease of middle and older age, with symptoms appearing in men around age 45 and women by age 55–60.[1,2] Every 2 years, for the next 50 years, up to 1.3 million people can expect to develop disabling PVD in the United States.[1] Symptoms vary with the extent of the disease. Intermittent claudication, pain felt in the calf while walking that is relieved with rest, is a hallmark symptom most frequently associated with PVD and is a strong diagnostic indicator of the disease.[3] The presence of intermittent claudication can severely limit one's ability to walk, ultimately leading to further impairment of peripheral circulation. Symptoms tend to worsen in 10–20% of people.[2] Staples of PVD treatment have included lifestyle change, vasoactive medications, and interventional radiological procedures or bypass surgery with grafting. The use of interventional procedures, such as arterial angioplasty or stent placement is limited to more severe cases. One year following angioplasty or stent placement, some 80–90% of patients maintain arterial patency.[3] Despite surgical and interventional advances, as many as 7% of all patients with PVD will go on to require amputation for critical limb ischemia within 5 years of symptom onset.[2]

The literature is rich with research investigating the effects of various treatments on PVD, with studies involving lifestyle change centering primarily on exercise (i.e., walking), smoking cessation, the use of medications to alter blood viscosity, and chelation therapy.[2–6]

Unfortunately, none of these studies has provided clear, consistent evidence of PVD symptom improvement. This has continued to fuel the search for new methods and alternative therapies that may decrease the pain and disability so often associated with progressive PVD.

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Effects of sound

Recently, healing effects from acoustic waveforms in a specific low frequency range were anecdotally noted in people experiencing various diseases or injuries. As a result, research has been undertaken to study the effects of audible sound on disease, specifically PVD.

Earlier investigations into the effects of sound on the body utilizing frequencies ranging from infrasound (inaudible less than 16 Hz) to ultrasound (inaudible greater than 20 mHz) were performed throughout the 1960s and into the 1970s and revealed no detrimental effects or safety hazards from whole body exposure for short periods of time.[7–10] Some researchers found that prolonged exposure to noise levels above 90 dB resulted in hearing loss.[11] However, it soon became clear that hearing impairment was only one of many important effects that sound could have on the body. Many of the later studies examined the physiological effects of sound on endocrine function in rats as well as humans, with some researchers finding increased activity of the corticoadrenal and adrenergic functions as well as an inhibition of the inflammatory response.[7,5,12,13]

Although some older studies can be cited, few, if any, have been conducted in the past 20 years. The model work presented in many of these studies supports the idea that sound at low frequency levels is no threat to health except for a loss of hearing sensitivity in those studies that use excessively high decibel levels for prolonged periods of time. None of these studies examined the effects of vibration and low frequency audible sound on disease.

Electroacoustic transducers are widely used in medical applications. Modern transducers often utilize the piezoelectric effect for converting electrical energy to acoustic energy. An alternating current applied to the material produces mechanical vibrations, in turn producing acoustic waves. Piezoelectric elements, therefore, are especially well suited to form the vibratory driving elements in electroacoustic transducers. Using new technology, the purpose of this study was to examine the effects of a low frequency acoustic waveform on PVD.

METHODS

Sample

Adult volunteers were recruited from the community through local newspaper advertisements, which requested that interested people with medically diagnosed PVD attend one of several scheduled 30-min information sessions. Institutional review board approval and informed oral and written consents were obtained from eligible participants.

The major inclusion criterion was a history of medically diagnosed PVD as confirmed by participants' statements. Exclusion criteria included: any previous acoustic waveform treatments, implanted devices, pregnancy, use of birth control pills, major surgery or trauma in the past year, prolonged immobilization during the past 6 months, or history of deep vein thrombosis.

Design

The pilot study utilized a one-group pre-intervention, post-intervention design. Researchers emphasized the importance of continuing usual patterns of activity and exercise, diet, hydration, rest, and medications prior to the study.

The setting for the study was a local facility housing the electroacoustic transducer (Fig. 1). On the day of the study, prior to the intervention, participants completed a brief background questionnaire. Arm and ankle blood pressures were obtained to determine baseline ankle brachial index (ABI) measurements. The ABI was calculated by dividing the highest systolic ankle pressure by the highest systolic brachial pressure. Generally, 1.0 or greater is normal, 0.5–0.9 represents mild to moderate disease, and less than 0.5 represents critical ischemia. Registered nurses completed routine color, movement, and sensation (CMS) peripheral circulation assessments of the feet. The assessment included palpation of skin temperature (warm, cool, and cold), color (flesh, pale, reddish, and bluish), and sensation (present or absent). To increase reliability, both nurses completed all assessments. Utilizing a Doppler flow ultrasound, both legs were examined by a certified ultrasound technician. The common femoral, superficial femoral, popliteal, tibial, and dorsalis pedis arteries were measured for flow velocity.[14] Following these pre-intervention measurements, participants were escorted to a room for the intervention. Thermostats were set consistently at 78 °F throughout the facility. However, ambient room temperature was not measured.

The intervention consisted of sitting in a chair for 25 min during which time the acoustic generator was turned on. Participants were asked to wear headphones through which relaxation music could be controlled by individual volume dials. Post-intervention measurements were taken for the same variables following the treatment. A 1-week follow-up telephone survey was conducted to assess any changes in PVD symptoms following the session.

Equipment

A portable Doppler ultrasound unit was used to measure blood flow velocity. Using a hand-held transducer, an ultrasound technician applied conductive gel on the area of vessel to be examined. The velocity was recorded on a screen in waveform patterns that correlated with flow centimeters per second. The pulsed flow ultrasound is not considered to be 100% exact because blood flow is pulsatile and is not

Fig. 1 Electroacoustic transducer.

uniform across the vessel. However, the calculated mean frequencies are highly reliable and are considered diagnostic in terms of evaluating the extent of peripheral artery disease (available online: www.mcbroom.btinternet.co.uk/medict/frames/Title.htm).

The intervention was performed using an electroacoustic transducer, which consists of a metal cylinder and sleeve that house an arrangement of hollow piezoelectric cylinders to form a piezoelectric stack. These vibrate together as a unit and provide the driving mechanism in achieving wall vibrations for the acoustic waves.

A key facet of this technology is the efficiency in which electrical energy is converted to mechanical movement. The transducer is capable of operating at high efficiency, while resonating at a specified frequency. Additionally, it resonates with an omnidirectional beam pattern. The frequency used in this study lies in the range from 500 to 800 Hz.

Instruments

A background questionnaire was developed by the researchers to gather information on age, gender, length of time diagnosed with PVD and symptoms associated with PVD. A brief follow-up survey was designed to assess PVD symptoms after 1 week. This 1-week time frame was selected based upon anecdotal reports of duration of symptom improvement. The survey utilized yes/no responses to a series of questions relating to PVD symptoms. The instruments were pre-tested on five adult members of the community for readability.

Data analysis

Blood flow data were analyzed using the SPSS statistical package for Windows®, release 10.0. Means and S.D. were calculated for the outcome variables. Independent *t*-tests were used to compare differences in outcome variables between pre- and post-test means. The Bonferroni correction to the alpha level (0.05/5) for each side involving the vessels was applied and the resulting alpha levels were set at 0.01. The ABI alpha level was set at 0.05.

RESULTS

Fifteen people meeting the criteria participated in the study. The 10 males and 5 females had a mean age of 73.9 ± 10.6 years. The length of time participants had been medically diagnosed with PVD ranged from 1 year to longer than 20 years, with a mean of 8.5 years. The participants reported a variety of PVD symptoms including pain, numbness, tingling, muscle fatigue, squeezing pressure, cramps, and swelling. Walking and standing were the positions most frequently reported to cause discomfort.

Incomplete data exist for several of the dependent variables because of the severity of disease and the difficulty in obtaining readings on many of the involved vessels. Therefore, the number of recorded measurements varied for each participant. Information on participants with complete pre- and post-intervention data is summarized in Tables 1 and 2.

Artery	Pre-intervention		Post-intervention		P-value
	Mean (cm/s)	S.D.	Mean (cm/s)	S.D.	
RCF (N = 15)	85.20	39.43	102.67	42.04	0.065
LCF (N = 15)	80.11	42.91	101.87	52.50	0.022
RDP (N = 13)	42.83	18.19	47.29	19.14	0.451
LDP (N = 15)	48.45	31.88	58.00	44.40	0.122
RPOP (N = 14)	48.73	27.42	58.29	32.37	0.016
LPOP (N = 15)	49.39	24.28	60.03	33.16	0.135
RSF (N = 14)	82.53	42.91	88.86	45.82	0.433
LSF (N = 14)	69.35	40.04	85.17	47.75	0.000
RPOSTIB (N = 8)	66.56	46.95	72.79	50.72	0.054
LPOSTIBA (N = 6)	56.33	40.61	78.47	26.99	0.045

Alpha level, $P \leq 0.01$. R, right leg; L, left leg; C, common; F, femoral; D, dorsalis; P, pedis; POP, popliteal; S, superficial; POS, posterior; TIB, tibial.

Table 2 ABI and raw values

Index	Pre-mean	S.D.	Post-mean	S.D.	P-value
RABI (N = 13)	0.90	0.36	1.00	0.28	0.050
LABI (N = 15)	0.85	0.35	0.93	0.35	0.246

Alpha level, $P \leq 0.05$. R, right; L, left; ABI, ankle brachial index.

Comparison of data

Comparisons of pre- and post-data for each of the vessels examined are reported in Table 1. The means of all participants' demonstrated changes in blood flow for all of the vessels examined. However, given the Bonferroni correction, a significant difference was found between pre- and post-measures for only 1 of the 10 vessels investigated: left superior femoral artery (LSF) ($P < 0.001$). Participants demonstrated significantly increased mean scores for the right ankle brachial index (RABI), ($P = 0.05$). The ABI data are reported in Table 2.

Little change was noted between the pre- and post-foot assessment. Three of the 15 participants experienced a change in foot color from pale to flesh color. Additionally, foot temperature improved from cool to warm on three participants. Lastly, three participants who initially felt no sensation to sharp touch were able to perceive the sharp sensation following the intervention.

Changes noted between pre-intervention symptoms and 1-week post-intervention symptoms are summarized in Table 3. Of the 15 participants, 13 reported improvement in one or more PVD symptoms during the week following the intervention.

Table 3 Self-report of PVD symptomology

Indicator	Pre-intervention (number of participants responding)		One week post-intervention[a] (number of participants responding)	
	Yes	No	Yes	No
Symptoms felt in legs				
Pain	10	5	7	8
Numbness	8	7	5	10
Tingling	5	10	3	12
Activities associated with discomfort				
Walking	12	3	9	6
Sitting	2	13	1	14
Standing	8	7	4	11
Lying down	1	14	1	14
Distance walked before feeling PVD symptoms				
Across room	2		1	
1/2 block	4		1	
One block	3		2	
More than one block	5		9	

[a] Duration of symptom improvement ranged from 2 to 5 days after intervention, one report lasting one full month.

Prior to the intervention, there were 23 reports of leg pain, numbness, or tingling. One week after the intervention, that number had dropped to 15, an overall reduction of 35%.

Participants were asked to identify the positions causing the most leg discomfort. Walking and standing were the most identified positions of pain, followed by sitting and lying down. In the 1-week telephone follow up, complaints of position discomfort with walking had decreased 25%, while standing and sitting position complaints had both dropped by 50%. For the one participant who experienced discomfort while lying down, no change was noted after 1 week. The distance that participants were able to walk before feeling PVD symptoms ranged from across the room to more than one block. Before the intervention, only five participants reported being able to walk more than one block before feeling PVD symptoms. One week later, nine participants reported that they could walk more than one block, an increase of 80%. The duration of symptom improvement ranged from 2 to 5 days, with one participant reporting improvement in walking distance and pain reduction for one full month.

DISCUSSION

The present study was designed to evaluate the effects of a low frequency acoustic waveform on PVD. Although a significant increase in blood flow velocity was only noted in one vessel as well as the RABI, it was demonstrated that exposure to the acoustic waves at the designated frequency increased the blood flow velocity pre to post in all of the 10 vessels examined. We are unable to corroborate the results obtained with other studies because of the novelty of this intervention. Studies involving infrasound (i.e., under 16 Hz) have yielded diverging results. Some of these researchers examined blood pressure changes during infrasonic exposure, reporting increased diastolic and decreased systolic pressures,[15] while others explored the effects of infrasound on the auditory and non-auditory systems.[9,16–19] However, the results of these studies cannot be extrapolated to the present study because frequency and pressure ratios (decibels) are very different.

The characteristics of acoustic frequency involved in the physiological reactions are mostly unknown. It is believed that peripheral vascular disorders involve changes in vessel structure and function. Therefore, conclusions must be viewed cautiously. The significant differences, however, certainly warrant further study.

The study had several limitations. The small sample size and lack of control group are threats to internal validity. There are numerous factors that affect blood flow velocity that the study did not attempt to control for, including underlying vessel size, stress level and endogenous hormone release, heart rate, cardiac output, hydration status, use of medications, diet, smoking status, use of herbs or vitamins, or the presence of concurrent diseases.

The relationship between warmth and vessel dilation is well documented. Although the individual room thermostats were set at 78 °F, room temperatures were not measured. The possibility of highly variable temperatures within the facility is a significant weakness in the study.

The follow-up telephone survey relied on participant recall of subjective information. While useful, this type of information would be strengthened through the use of more objective data, such as follow-up ultrasound, ABI, and nursing assessment of the feet. The use of dichotomous responses limited the range of data that could be obtained. A revised survey should include range-type responses. This will make the survey more sensitive to degrees of symptoms versus merely presence of symptoms.

Based on these preliminary findings, a larger scale study has begun which is double blinded and utilizes randomized control and treatment groups. The study should yield more objective information in determining the acoustic wave effects in alleviating PVD symptoms.

ACKNOWLEDGEMENTS

The authors wish to thank Mr. Al Cassone for his assistance in the completion of this study.

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